

REMARKS

Upon receipt of this response, the Examiner is respectfully requested to contact the undersigned representative of the Applicant to arrange a telephone interview concerning the inventive merits of this application.

Claims 15-16, 18-19, 21, 27, 29-30 and 32-36 are rejected, under 35 U.S.C. § 103, as being unpatentable over Berke `400 (US Patent No. 5,165,400) in view of Tomic-Edger et al. `144 (US Patent No. 2,677,144 B1) and Irani `370 (US Patent No. 5,405,370). The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the above amendments and the following remarks.

Initially it is noted that the claims have been amended to define the "patient" as being a "small animal". There is clear support in the specification for the words "small animal" as such, this limitation does not introduce new matter into the case.

Further, the term "small animal" is a well known and well used term in the veterinary art. The term "small animal" also has a specific meaning to veterinarians (the "skilled person" in the veterinary art) which defines a specific size of animals. As such veterinarians are well aware what a small animal means (eg cats, small dogs, etc).

In rejecting the claims the Examiner submits that, firstly, it would be obvious to combine the disclosure of Berke `400 with the disclosure of Tomic-Edger et al. `144, and insists that this combination teaches the claimed feature that "the warmed air is delivered to the patient receiving space via the entire surface of the porous material".

As the Examiner is well aware if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Further, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

The Applicant asserts that first, modifying the convective hypothermia article of Berke `400 as proposed to include the porous material, as disclosed by Irani `370 would render the convective hypothermia article of Berke `400 unsatisfactory for its intended purpose. Second, modifying or combining the porous material as disclosed by Irani `370 with the convective hypothermia article of Berke `400 would change the principle of operation of the convective hypothermia article as taught by Berke `400. Therefore, the Applicant avers that there is no

suggestion or motivation to make the proposed modification as suggested by the Examiner nor are the teachings of Berke `400 and Irani `370 are sufficient to render the claims prima facie obvious. The Applicant respectfully requests withdrawal of the pending 35 U.S.C. 103 rejections and withdrawal of the finality of the outstanding official action.

The intended purpose of the convective hypothermia article of Berke `400 is to warm a patient while allowing unhindered access to the patient during treatment by medical professionals. As discussed by Berke `400 one of the issues with known prior art means of treating hypothermic patients (blankets) was that the blankets were difficult to use while at the same time treating the patient via IV tubing or other life support equipment (col. 1, Ins. 39-43). The purpose is achieved by the convective hypothermia article by partially positioning the convective hypothermia article around the patient (col. 2, Ins. 64-65) such that it does not come into contact with the patient (col. 3, Ins. 15-18). The convective hypothermia article comprised a number of air holes such that a maximum flow of warm air was directed at the patient (col. 3, Ins. 63-65). In sum, the convective hypothermia article of Berke `400 operates by directing jets of warm air to achieve the purpose of heating the patient while at the same time allowing a medical professional complete access to the hypothermic patient.

Irani `370 relates to an air blanket made of a porous material which is superposed over a patient and which covers the entire length of the patient (col. 2, Ins. 65-68). As noted by the Examiner, the porous material diffuses air which gently impinges on the patient over the entire surface covered by the air blanket (col. 3, Ins. 60-63).

The Applicant asserts that the porous material used with the air blanket taught by Irani `370 when combined with the convective hypothermia article of Berke `400 would render the convective hypothermia article of Berke `400 unsatisfactory for its intended purpose and change the principle of operation of the convective hypothermia article.

For these reasons the Applicant adamantly asserts that the porous material as taught by Irani `370 when combined with the convective hypothermia article of Berke `400 would render the convective hypothermia article unsatisfactory for its intended purpose and change the principle of operation of the convective hypothermia article. As such, the Applicant again respectfully requests withdrawal of the pending 35 U.S.C. 103 rejections and withdrawal of the finality of the outstanding official action.

Further, where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*,

927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). The Applicant asserts that the references of Berke `400 and Tomic-Edger et al. `144 teach away from Irani `370.

It is noted that Berke `400 discusses treating patients with the use of blankets such as the blanket taught by Irani `370 (col. 1, Ins. 47 - col. 2, In. 9). Berke `400 states that these blankets have drawbacks such as heat retention effectiveness, cost of construction strength of materials, bulkiness weight and ease of use (col. 3, Ins. 13-17). Next, although Tomic-Edger et al. `144 teaches treating patients using blankets, Tomic-Edger et al. `144 also discusses the several disadvantages of such thermal treatment systems. One of these drawbacks is that these treatment systems (blankets) fail to deliver heat to the patient without encumbering access to the patient's body (col. 1, Ins. 16-18). To overcome this drawback, Tomic-Edger et al. `144 teaches a thermal conducting apparatus that uses three cover portions to cover the patient, "if access to the patient's body is not needed" (col. 4, Ins. 44-45). As taught, these cover portions are merely regular type blankets made of any thermally insulative material (col. 3, Ins. 33-37). They do nothing more than cover the patient when the patient is not otherwise being treated by a medical professional. The thermal conditioning apparatus taught by Tomic-Edger et al. `144 is otherwise essentially the same device taught by Berke `400 and comprises orifices to deliver a thermally conditioned medium to the patient (col. 3, Ins. 29-31). In other words, thermal conditioning apparatus directs a flow of heated air over the patient.

In opposition to teachings that are substantially the same as those of Berke `400 and Tomic-Edger et al. `144, the reference of Irani `370 teaches a device with which heated air is softly and gently diffused over the patient instead of being jetted across the patient in a plurality of discrete air streams (col. 2, Ins. 7-14). As such, the Applicant asserts that the references of Berke `400, Tomic-Edger et al. `144 and Irani `370 teach away from each other.

Continuing, the Applicant disagrees with the Examiner and does not believe that this combination would be obvious, as there appears to be no motivation to combine Berke `400 and Tomic-Edger et al. `144. Nevertheless, as observed by the Examiner, even if the combination were made, it does not teach all of the limitations as claimed in claim 15. As noted by the Examiner the combination of Berke `400 and Tomic-Edger et al. `144 fails to teach the claimed limitation that "the warmed air is delivered to the patient receiving space by diffusing over the entire surface of the porous material at a relatively low velocity so as to have the effect of evenly warming the patient without forming relatively high velocity streams of air".

The Examiner further cites Irani `370 which teaches a blanket 10 having a heat transfer layer 28, which is arranged such that air from a chamber 26, which is internal to the blanket, penetrates and uniformly diffuses through the heat transfer layer 28 to impinge upon the treated

patient. The Examiner submits that it would be obvious to take the heat transfer layer of Irani `370 and combine it with a blanket as taught by the combination of Berke `400 and Tomic-Edger et al. `144, to result in a combination which falls within the definition of current claims.

The Applicant respectfully submits, firstly, that the combination of Berke `400, Tomic-Edger et al. `144 and Irani `370 is not an obvious. Secondly, even if the combination of all three of these references were permissible, contrary to the Applicants belief, the combination would still not result in disclosing all the features of claims.

The Applicant contends that the above combination is not obvious and is impermissible for a number of reasons:

1. A combination of features from three different references is required. None of the references cite any of the other references. It is respectfully submitted that such a combination would only be made in hindsight given the knowledge disclosed by the present invention. It is asserted that such a combination would not be made by a skilled person working in the art at the time of the priority date of the application. To make such a combination, of three different documents, which do not reference each other, surely indicates that the combination is actually an inventive one! The Applicant respectfully submit that such "*ex-post facto* analysis" of inventions is impermissible and avers that the prior art must suggest, teach, or motivate one to combine the prior art. *In re Dembiczak*, 175 F.3d 994; *In re Rouffet*, 149 F.3d 1350

2. Even if person of ordinary skill in the art were to consider the disclosure of the three documents together, that person would appreciate that the heat transfer layer 28 of Irani `370 would not be a suitable material for use with the type of articles disclosed by Berke `400, Tomic-Edger et al. `144. A person of ordinary skill in the art would realize that if the heat transfer layer 28 as taught by Irani `370 was substituted for the materials for the elements with air holes punched in them of Berke `400, Tomic-Edger et al. `144, the articles of these two references would not operate adequately to heat a patient within the patient receiving space defined by Berke `400, Tomic-Edger et al. `144. See the below explanation regarding the operation of the heat transfer layer 28 of Irani `370. The Applicant submits that a person of ordinary skill in the art would therefore not consider the combination to be a useful one and would not make it.

3. The blanket of Irani `370 has a totally different method of operation in comparison to the articles of Berke `400 and Tomic-Edger et al. `144. On one hand, the blanket of Irani `370 requires that the heat transfer layer 28 retain heat and then the

heated air is slowly diffused through the heat transfer layer 28 to circulate the heat over the treated patient. On the other hand, the articles of Berke '400 and Tomic-Edger et al. '144 require that a large volume of air be quickly passed through the holes in the material into the patient receiving space to heat the patient. Berke '400 and Tomic-Edger et al. '144 do not require that the surfaces of their articles retain heat. In fact this is a disadvantage, as the heat needs to be supplied by the air to the patient receiving space formed by the articles. The Applicant again submits that a person of ordinary skill in the art would combine the cited references in the manner suggested by the Examiner.

Even if the references were properly combined (which the Applicant does not agree would be the case) the combination of teachings of Berke '400, Tomic-Edger et al. '144 and Irani '370 would still not result in a warming blanket comprising all the features recited in the claims.

The claims recite that the warmed air diffused sufficiently to evenly warm the patient in the patient receiving space. For this to be achieved a sufficient volume of air must be delivered to the patient receiving space. If the material of Irani '370 were used with the articles of Berke '400 and Tomic-Edger et al. '144, the material would not allow for a sufficient volume of air to be diffused into the (open) patient receiving space to achieve even warming of the patient. In fact, it is highly unlikely the patient would be warmed at all significantly. This is because the heat transfer layer 28 of Irani '370 is arranged to capture and retain heat as discussed below.

The Applicant asserts that the operation of the heat transfer layer 28 of Irani '370 is vastly different from the teachings of Berke '400 and Tomic-Edger et al. '144. A fundamental distinction between the air blanket of Irani '370 and the heating articles of Berke '400, Tomic-Edger et al. '144 and the present invention as claimed, is that Irani '370 discloses a blanket which is arranged to cover a patient and essentially trap the heated air, whereas the articles of Berke '400, Tomic-Edger et al. '144 and the present invention as claimed are arranged to provide or direct heated air into an open patient receiving space. In these arrangements, the air itself must transport sufficient heat to warm the patient. In Irani '370, as with other systems where blankets cover a patient, the blanket itself is arranged to retain and provide a large proportion of the heat to heat the patient. With Berke '400, Tomic-Edger et al. '144 and the present invention as claimed, the patient is only heated by air impinging upon the patient from the article, while the article itself does not provide any heat to the patient in the manner of a typical blanket such as the blanket of Irani '370. Articles such as those taught by Berke '400 and Tomic-Edger et al. '144 and claimed by the present invention, therefore, need to address

a totally different problem from that of the article of Irani '370. They need to be able to provide sufficient air to heat, by way of the air, an open patient receiving space. In contrast, Irani '370 and other typical blanket type arrangements, can use heat retained by the blanket to maintain the heat of the patient. As such, they need to provide only very low volumes of heated air.

Irani '370 is essentially a heated blanket.. A typical electric blanket (ie one with electrical heating elements) would provide essentially the same function as the blanket of Irani '370.

The blanket type approach of Irani '370 as used in the prior art discussed in the background of the invention section of Irani '370 (columns 1 and 2). For example, the airflow device as disclosed in US Patent No. 4,572,188 is sold commercially with a recommendation that a surgical drape overlie the blanket. That is, the known airflow device needs a blanket in addition to the heated air that is passed therethrough (see column 1, lines 44-46).

The main problem solved by the blanket of Irani '370, is that it does not require the additional use of an overlying surgical drape or blanket (see column 2, lines 1 and 2). This is because the heat transfer layer 28 in fact combines the operation of a blanket with a porous material for receiving and diffusing heated air.

The heat transfer layer 28 of Irani '370 is in fact of quite a complex construction, and comprises a laminate construction of a web material and a core composed essentially of a web or textile (eg it could be wool or paper). Further, on either side of the core there is an abrasion resistant, fiber containing surface region (see column 2, lines 15-27). It is clear that the structure of the blanket of Irani '370 is arranged to capture or retain heat. See in particular column 5, lines 15-20.

Irani '370 teaches a heated blanket, which uses air to heat the blanket, and diffuses the warm air and heat from the blanket over the patient. The type of material which forms the heat transfer layer is such material as "Kleenguard" developed by Kimberly Clark. This type of material would not handle the volumes of air that are required to be provided to the patient receiving space by Berke '400 and Tomic-Edger et al. '144 and the article claimed by the present invention

The blanket as claimed in the present application is comprised of thin layers (eg polyester layers) and is only arranged so as to weigh a few ounces and have no heat retaining capacity. All the heat provided by the claimed heating unit to the patient receiving space is provided by the volume of air flowing to the patient receiving space. In fact, to maintain animal/human temperatures roughly between 38° and 46°C, requires the delivery of about 300-

500 liters per minute of air to the patient receiving space. The heat transfer layer of Irani '370 is not capable of delivering this volume of air without rupturing. This is because heat transfer layer is a complex and relatively thick layer of material. Although one could argue that air may diffuse through the layer, it would not pass in sufficient volumes to carry out the function as claimed in the application, nor does the air in Irani '370 blanket need to diffuse at such a high volume, because the blanket retains the heat retention, ie Irani '370 is essentially a heated blanket.

Even if one were to combine the teachings of the combination of Berke '400, Tomic-Edger et al. '144 and Irani '370, the Applicant asserts that the combination still does not teach the feature required by the claims of the air to have the "effect of evenly warming the patient". This is because the "patient receiving space" is surrounded by the tubular arrangement. The tubular arrangement is not a blanket such as that of Irani '370 which covers the patient receiving space. The patient receiving space must be "open allowing access to the patient's body for surgery without disturbing the blanket".

It is respectfully submitted that since all the other claims of the application are either dependent on claim 15 or include similar features, these are also not obvious in the light of the suggested combination of Berke '400, Tomic-Edger et al. '144 and Irani '370.

Claims 22-36 and 37 are rejected, under 35 U.S.C. § 103, as being unpatentable over Berke '400, Tomic-Edger et al. '144 and Irani '370 in view of Hagopian '997 (US Patent No. 4,963,997). The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the above amendments and the following remarks.

The Applicant acknowledges that the additional reference Hagopian '997 of may arguably relate to the features indicated by the Examiner in the official action. Nevertheless, the Applicant respectfully submits that the combination of the base references of Berke '400, Tomic-Edger et al '144 and Irani '370 with this additional art of still fails to in any way teach, suggest, disclose or remotely hint at the above distinguishing features of the presently claimed invention.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejections should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejection(s) or applicability of the Berke '400, Tomic-Edger et al '144, Irani '370 and Hagopian '997 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied

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references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,



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